



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/095,801 07/20/93 LANGLEY

EXAMINER
K BIASCUP

PRIORITY, R

ART UNIT	PAPER NUMBER
1814	14

DATE MAILED:

09/21/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 9/7/93 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-39 are pending in the application.
Of the above, claims 1-11, 14, 27-29, 31-34 and 36-39 are withdrawn from consideration.
2. ☐ Claims — have been cancelled.
3. ☒ Claims 35 is are allowed.
4. ☒ Claims 12, 13, 15-19, 21-26 and 30 are rejected.
5. ☒ Claims 20 is are objected to.
6. ☐ Claims — are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on —. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on — has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on —, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. —; filed on —.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-11, 14, 27-29, 31-32, and 36-37 drawn to metalloproteinase inhibitor protein, classified in Class 530, subclass 324.

II. Claims 12-13, 15-26, 30 and 35, drawn to DNA sequences, vectors and host cells and expression of metalloproteinase inhibitor protein, classified in Class 435, subclass 69.2.

III. Claims 33 and 34, drawn to a method of inhibiting metastasis and a method of treating arthritis, classified in Class 514, subclass 12.

IV. Claims 38 and 39, drawn to antibodies, classified in Class 530, subclass 380.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the product as claimed can be made by a materially different process such as chemical synthesis.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or

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both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the protein may be used in inhibiting cancer metastasis, or in treating arthritis.

Inventions I and IV are chemically distinct entities and would support separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicants' election of Group II, claims 12-13, 15-26, 30 and 35, in parent application Serial No. 07/501,904 is assumed to carry over to the instant application. See 1046 TMOG 2. Accordingly, claims 12-13, 15-26, 30 and 35 are considered on the merits and claims 1-11, 14, 27-29, 31-34 and 36-39 are withdrawn as being drawn to nonelected inventions.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make the claimed invention. Claim 23 claims polypeptide fragments and analogs of metalloproteinase inhibitor (MI). This term is so broad as to include virtually any type of modification known, including insertions, deletions, mutations, and chemical modifications. No guidance is provided as to what portions of the disclosed protein can be modified without changing the activity of the protein nor of what types of modifications are likely to produce an active protein. Therefore, undue experimentation would be required of one skilled in the art to make fragments and analogs of the MI protein disclosed. Furthermore, Claims 12, 13, 15-19, 21-22, 25-26 and 30 are currently sufficiently broadly stated as to also include fragments and virtually any analogs of human MI.

Claims 12, 13, 15-19, 21-26 and 30 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification. It is suggested that all of these claims be limited to read on only the DNA encoding the amino acid sequence of the entire human MI protein shown in Figure 2.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that

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the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 12, 13, 23-26 and 30 are again rejected under 35 U.S.C. § 103 as being unpatentable over Murray et al. in view of Kimmel for the reasons made of record in the previous office action as these claims are not limited to the expression of human MI and the combined disclosures of Murray et al. and Kimmel make obvious the cloning and expression of the gene for the bovine MI protein disclosed by Murray et al. Applicants amendments to Claim 12 (from which all of these claims depend) filed on 9/7/93 does not overcome the previous rejection because bovine MI, as taught by Murray et al., clearly has at least a part of the primary structural conformation (defined as having an amino acid sequence at its amino terminus of at least amino acid residues 1 to 42 of Figure 2) and all of the biological properties of

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naturally occurring MI and will hybridize under stringent conditions to the gene for human MI.

Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 35 is allowable over the prior art of record.

This is a continuation of applicant's earlier application S.N. 07/501,904. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See M.P.E.P. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D., whose telephone number is (703) 308-4000.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



ROBERT A. WAX
SUPERVISORY PATENT EXAMINER
GROUP 180